



U.S. Department  
of Transportation  
**Research and  
Special Programs  
Administration**

400 Seventh St., S.W.  
Washington, D.C. 20590

APR 22 2002

Shanna Nesby-O'Dell DVM, MPH  
Chief, External Activities Program  
Office of Health and Safety  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, Georgia 30333

Dear Dr. Nesby:

This responds to your emails and telephone conversations with Ms. Susan Gorsky of my staff concerning requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) for transporting diagnostic specimens. Specifically, you are concerned about the shipment of elk fetuses that may be infected with *Brucella*.

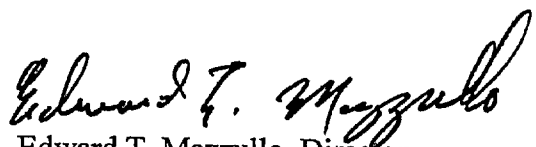
A diagnostic specimen, even one known to contain an infectious substance, is excepted from the requirements of the HMR unless the material meets the definition of another hazard class (§ 173.134(b)(1)(ii)). "Diagnostic specimen" means any human or animal material, including excreta, secretions, blood, blood components, tissue, and tissue fluids being shipped for purposes of diagnosis. It is our understanding that the elk fetuses at issue are part of a research study of the effectiveness of a *Brucella* vaccine and are being transported for analysis to determine if they are, in fact, infected. Under these circumstances, the elk fetuses are considered diagnostic specimens for purposes of the HMR and are excepted from regulation under the HMR.

You asked us to evaluate the packaging the shipper plans to use to transport the elk fetuses. The elk fetuses will be frozen and packed inside a securely closed primary biohazard bag. The primary biohazard bag is then placed inside a securely closed secondary biohazard bag. The biohazard bags are then placed inside a lined Styrofoam cooler, with absorbent material to completely fill the cooler. The cooler is then placed inside a cardboard shipping box. Since diagnostic specimens are excepted from regulation under the HMR, no specific packaging requirements are prescribed. The packaging described appears to be sufficient to withstand conditions that may occur during transportation.

Moreover, it is our understanding that the carrier (FedEx) that will be transporting the elk fetuses has approved the packaging for shipment of diagnostic specimens.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

A handwritten signature in black ink, reading "Edward T. Mazzullo". The signature is written in a cursive, flowing style with a large, prominent "M".

Edward T. Mazzullo, Director  
Office of Hazardous Materials Standards

# Memorandum

27 March 2002

To: List  
From: T.J. Roffe  
Cc:

Subject: Strain 10 elk fetus shipping protocol

We reconfirmed the requirements for shipping diagnostic specimens via Fed Ex this AM, including labeling requirements. Diagnostic specimen samples require a leakproof primary container (we will use 5 or 7 gallon biohaz bags, depending on fetus size), a leakproof secondary container (5 gallon or a 7 gallon biohaz bag, depending on fetus size), absorbent material (we will use shredded paper), and cardboard shipping container. We will also use a tertiary bag for each external shipping container and all shipping containers will be lined with 2 inches insulating foam.

## Protocol:

1. Only authorized personnel may ship. These include: Thomas Roffe, Mark Drew, Steve Sweeney, Lee Jones, Maryanne Hoagland and Julia Mulholland.
2. Shipping may only occur on Monday, Tuesday and Wednesday. Monday and Tuesday are preferred.
3. Call LSU to confirm they are prepared to receive shipment and relay your intended shipping day and time.
4. Call FedEx Boise to confirm latest time for receipt of box for Priority Overnight Delivery.
5. Each fetus should be in a primary biohaz bag that is twisted into a long neck, folded over on itself, and double cable-tied (ties about 1-2 inches apart). Cable ties should be left long (untrimmed) so that the end is pliable with no sharp edges.
6. Place primary container into a secondary biohaz bag that is similarly closed.
7. Ensure fetus is solidly frozen before further packing (refer to fetus collection protocol for transferring fetus from pens to WHL freezer).
8. Remove the styrofoam cooler from the cardboard box and remove lid off cooler.
9. Place a layer of absorbent material in the bottom of the cooler.
10. Place the drum liner (heaviest gauge puncture resistant plastic available - designed for lining chemical drums) into the cooler, and cut off excess plastic at the top (leaving enough to close with cable ties as above).
11. Place absorbent material in the bottom of the drum liner.

12. Two or three frozen fetuses (depending on size), each enclosed in their primary and secondary enclosures (see above), should be placed into the drum liner on top of the absorbent material.
13. Place more absorbent material around and on top of the fetuses sufficient to fill open space and prevent shifting of contents during shipment. Pack absorbent material between fetuses if space is available.
14. Close the drum liner as described for primary and secondary containers.
15. Place the lid on the styrofoam cooler and tape the lid of the styrofoam cooler to the body of the cooler, both across the top in both directions, and a strip of tape around the seal between the lid and cooler. Use only Premium Heavy Duty Packaging tape which adheres well to itself and styrofoam
16. Place the taped styrofoam cooler into the cardboard shipping box.
17. Tape the top of the box shut securely using Premium Heavy Duty Packaging tape.
18. Place one red "fragile this side up" sticker on each side of the cooler.
19. Air Bill labeling:
  - Item 1: fill in date, account number, your name, phone, USGS, 16569 S. 10th Ave. Caldwell, ID 83607.
  - Item 2: leave blank
  - Item 3: Dr. Phil Elzer, 225-578-5429, LSU Veterinary Science, 111 Dalrymple Bldg., Baton Rouge, LA, 70803
  - Item 4: check FedEx priority overnight. Leave item 4b blank
  - Item 5: check "other package"
  - Item 6: check "no" under Dangerous Goods
  - Item 7: check "sender", FedEx will fill in package and weight info
  - Item 8: leave blankPlace complete air bill in FedEx airbill window.  
FedEx does not require any further labeling for diagnostic specimens.
20. Affix FedEx window with shipping airbill (containing all relevant info) on top of the box. Do not remove top strip of window adhesive backing!
21. Transport packages to FedEx, Boise Airport ½ hour prior to latest drop off time.
22. FedEx will remove and finish airbill after weighing. Take Senders copy as your receipt.
23. Call LSU to confirm shipment is on its way and request receipt notification.
24. Track each box via the FedEx website, and print out a copy of the confirmation from the website when received by LSU. Confirmation page provides you information on who signed for the box and when. This double tracking will ensure receipt notification. Attach confirmation page to Senders copy of air bill and return to Lee Jones.

## Gorsky, Susan

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**From:** Nesby, Shanna [sln1@cdc.gov]  
**Sent:** Monday, April 08, 2002 11:20 AM  
**To:** 'Valerie.E.Ragan@aphis.usda.gov'; 'Barbara.M.Martin@aphis.usda.gov';  
'Susan.Gorsky@RSPA.dot.gov'  
**Cc:** Nesby, Shanna  
**Subject:** FW: Shipping fetuses

Susan/Barb/Val, (In reference to the following thee e-mails below)

As I mentioned, we/CDC consider DoT to be the experts on appropriate packaging methods and we'll yield to their guidance if DoT will provide a letter approving the proposed packaging. Otherwise, I think we should proceed with a letter from USDA/CDC offering the 3-options:

- (1) Locate appropriate 6.2 containers (ask if resources are a problem) and ship whole carcasses by air;
- (2) Take tissues (at Cane Center) and ship tissues by air using appropriate 6.2 containers;
- (3) Arrange for ground transportation using alternate packaging methods approved by DoT.

-Shanna-

-----Original Message-----

**From:** Roffe, Tom [mailto:troffe@montana.edu]  
**Sent:** Monday, April 08, 2002 10:17 AM  
**To:** 'Susan Gorsky'; 'Nesby Shanna'  
**Cc:** Cushmac George  
**Subject:** RE: Shipping fetuses

But do you see the problem I face, Susan? You say if I can make arrangements with FedEx great, but then I keep getting these messages saying there is a regulatory requirement that we use a labeled class 6.2 outer container and ship as dangerous goods. I have personally sat down with the FedEx Dangerous Goods inspectors. I've laid out the research, told them what we were doing, told them that these are fetuses that could potentially contain brucella, told them how we plan to package them, etc. They have no concerns. The honest truth is they are only concerned about what the regulatory agencies are going to call the package, and therefore what regulations they will have to follow without fear of regulatory retribution. In our discussions with FedEx and with a hazardous materials shipper in Boise no one has expressed concern over our packaging and all, in fact, have simply said why don't we ship these using standard outer containers (the ones I describe in our protocol). That means, according to regulatory citations, they have to go as diagnostic specimens. And since that is the real, honest to god reason for shipping them I don't see a problem with our protocol. But as I said to Shanna, I will wait to hear what George has to say about our protocol. Or if either of you wants to comment, please feel free. I am really trying to just get this done while maintaining adequate but reasonable biosecurity. Thanks for your comments.

I'll be in Idaho all week, but will have my email via laptop. Or try my cell phone if someone needs me.

tjr

Thomas J. Roffe, PhD, DVM  
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FWP Bldg, 1400 S. 19th Ave.  
Bozeman, MT 59718-5496

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F: 406-994-4090

Cell: 406-539-4955

-----Original Message-----

From: Susan Gorsky [mailto:Susan.Gorsky@RSPA.dot.gov]  
Sent: Monday, April 08, 2002 6:11 AM  
To: 'Roffe Tom'; Gorsky Susan; 'Nesby Shanna'  
Cc: Cushmac George  
Subject: RE: Shipping fetuses

Dr. Roffe,

If you have been able to make arrangements with Fed Ex for shipping your elk fetuses, that is great. My only purpose in sending the previous email was to notify both you and Dr. Nesby that, even though diagnostic specimens are excepted from regulation for purposes of transportation under the Hazardous Materials Regulation, they are treated differently in international standards and by many domestic air carriers. Good luck with your research.

Susan Gorsky

-----Original Message-----

X-Sybari-Space: 00000000 00000000 00000000 00000000  
From: Roffe, Tom [mailto:troffe@montana.edu]  
Sent: Sunday, April 07, 2002 6:54 PM  
To: 'Susan Gorsky'; 'Nesby Shanna'  
Cc: Cushmac George  
Subject: RE: Shipping fetuses

I just returned from travel in Utah. It's Sunday evening and I see we are still going through this. Sigh... there are no manufacturers that produce such labeled containers, Dr. Gorsky, for the size we need; we've contacted them all. FedEx will handle our material - we have discussed this with the FedEx dangerous goods inspectors at the airport. Their concern, flat out, is what do you call it thus to what regulations will they be held. They are not concerned with our packaging. It is interesting how this has become a test of semantic wills rather than any real (at least expressed to me) concern over our packaging methods. No one has said "here are the inadequacies of your packaging", only "follow this regulation even though that's impossible". FedEx's only concern is who holds the regulatory club that will compromise their business. We confirmed, for the 3rd time, with the dangerous goods inspectors that we can take experimentally challenged elk aborted fetuses and ship them to LSU to "confirm, verify or diagnose" whether they have brucellosis as diagnostic specimens. But, of course, only if that regulatory club isn't going to come crashing down on their head.

I also must point out that you are correct, but incomplete, in your statements, Dr. Nesby regarding 42 CFR 72:

42 CFR 72.1 Definition of a Diagnostic Specimen: "any human or animal material including, but not limited to, excreta, secret, blood or its components, tissue, and tissue fluids being shipped for the purposes of diagnosis". The one, and only, purpose to ship these specimens to LSU is to determine whether, if, or do they contain Brucella. There is certainly nothing in the CFR that says if the diagnostic specimen is derived from the field then it is a diagnostic specimen, but if derived from an experiment it is not.

Yes, 42 CFR 72.2 says "no person may knowingly transport or cause to be transported, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may contain an etiologic agent". But the rest of the statement says "unless such material is packaged to withstand leakage of contents, shocks, pressure changes and other conditions incident to ordinary handling in transportation." I have shipped specimens nationally and

internationally over the last 20 years and have no circumstances of leakage under "ordinary handling in transportation". There is also nothing in 42 CFR 72 that requires a specifically labeled container.

Further, 42 CFR 72.6(h)(1)(i) states: "select agents otherwise covered by this part [and this is part 72] are exempt from its provisions if the agent is part of a clinical specimen intended for diagnostic, reference or verification purposes". Here, again, it is quite clear that even if you suspect a select agent, expect a select agent, but you need to verify its presence, you are exempt. I hate to repeat myself, but there is NO other reason to ship these fetuses to LSU. I would love to just tell folks CDC says they are brucella infected so we didn't have to do diagnostic bacteriology. Unfortunately, no one will accept that.

Why are we getting into this interpretive battle? Isn't the goal really human safety? Dr. Nesby, you acknowledged the reality of brucellosis in the wild in the United States, the fact we handle and ship field strain infected fetuses (no, not known beforehand, but certainly suspect), the oxymoron of such stringent conditions for experimental derived tissues when the organism is free for the asking in the wild and we deal with it daily. I have followed, and will follow at taxpayer expense, everything we can logistical, feasibly do for shipping this material. Can we just get a reading from George Cushmac on my shipping protocol I sent a week ago? George, if there is something lacking in the procedure, something you want me to do that I can do, please let me know and I will make it happen. I'm good, but I just can't make the impossible happen - liking shipping a fetus in a Dangerous Goods external container that will not fit the fetus.

tjr

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-----Original Message-----

From: Susan Gorsky [mailto:Susan.Gorsky@RSPA.dot.gov]  
Sent: Monday, April 01, 2002 11:00 AM  
To: 'Nesby Shanna'  
Cc: 'troffe@montana.edu'; Cushmac George  
Subject: RE: Shipping fetuses

Dr. Nesby,

I don't know how helpful we can be in identifying packaging alternatives. Dr. Roffe's best bet is probably to talk to FedEx and also to contact some vendors who specialize in manufacturing certified UN specification packagings for infectious substances. Two vendors are SAFTPAK (1-800-814-7484; www.saftpak.com) and ICC (1-888-442-9628; www.compliancecenter.com). (Note that DOT does not endorse packaging vendors.)

Susan Gorsky

-----Original Message-----

X-Sybari-Trust: e0073876 1973d0d1 a8f48997 0000003d  
From: Nesby, Shanna [mailto:sln1@cdc.gov]  
Sent: Monday, April 01, 2002 12:51 PM  
To: 'Susan Gorsky'; 'troffe@montana.edu'  
Cc: Foster, Joseph A.; 'Valerie.E.Ragan@aphis.usda.gov';

'Barbara.M.Martin@aphis.usda.gov'; 'Elzer'; mdrew@agri.state.id.us;  
'pelzer@aqctr.lsu.edu'  
Subject: RE: Shipping fetuses

Susan - Thanks. As I've explained, CDC does not consider these samples to be diagnostic specimens since they are directly tied to a research protocol. CDC is very critical about distinguishing research sample from clinical samples, in compliance with 42 CFR 72. In general for Select Agents, we consider clinical (or diagnostic) samples to have a direct outcome on: immediate physician/patient care, food safety (e.g. food poisoning), or law enforcement investigative procedures. These fetuses do not fall into any of the above categories. CDC will work with Dr. Roffe to achieve safe transport the fetuses (or tissues) under the required DoT and IATA regulations.

Tom - Why don't you give Dr. Kirshmack(?-spelling) a call to see if he can suggest appropriate alternatives (based on his past experience). His number is (202)366-4493.

I'm in my office all day if we need to talk and I travel up to USDA-Ames tomorrow (where I can be reached by pager 404-280-7294).  
-Shanna-

-----Original Message-----

From: Susan Gorsky [mailto:Susan.Gorsky@rspa.dot.gov]  
Sent: Monday, April 01, 2002 11:48 AM  
To: 'Nesby Shanna'  
Cc: 'troffe@montana.edu'  
Subject: RE: Shipping fetuses

Dr. Nesby,

I am working on a letter responding to your request that we evaluate the packaging proposed for the shipment of the elk fetuses. In reviewing Thomas Roffe's proposal, I note that he is planning to ship the fetuses by FedEx. You and he should know that FedEx requires hazardous materials shipments to conform to requirements in the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), even when shipping hazardous items domestically. The ICAO Technical Instructions require a diagnostic specimen that is known or reasonably suspected to contain a pathogen in Risk Group 2, 3, or 4 to be classed as a Division 6.2 (infectious substance) material. Under the ICAO Technical Instructions, a Division 6.2 material must be transported in conformance with Packing Instruction 602. Among other requirements, Packing Instruction 602 specifies that the packaging used to transport a Division 6.2 material must be capable of passing certain design tests, including a drop test and a puncture test, and must be marked to certify that it passed the design tests (UN specification packaging). Further, the package must be marked with the words "Infectious Substances, affecting animals only (Brucella), UN 2900" and labeled with an INFECTIOUS label. It is my understanding that there is a reasonable expectation that some or all of the elk fetuses are infected with Brucella. If so, and if the shipper plans to transport the fetuses by air, it is likely that the shipments will be required to conform to requirements in the ICAO Technical Instructions. If does not appear that the packaging proposed meets the UN specification requirements. The shipper should consult with FedEx to determine exact requirements.

I hope to have a formal letter signed this week. Please let me know if you need any additional information.

Susan Gorsky

-----Original Message-----

X-Sybari-Trust: 23a05063 1973d0d1 cf332e3a 0000003d



From: Nesby, Shanna [mailto:sln1@cdc.gov]  
Sent: Wednesday, March 27, 2002 9:06 PM  
To: 'Susan Gorsky'; 'Susan.Gorsky@rspa.dot.gov'; 'Roffe, Tom'; Foster, Joseph A.; 'George.Kirshmack@rspa.dot.gov'  
Cc: 'Carter, Jon'; 'mark d'; 'bob h'; 'val r'; 'barb m'; 'phil e'; 'dick j'; 'larry l'; 'debra h'; Hill, Robert H. Jr. (OD); de Peyster, Frances L.; Boll, Deborah A.; Ostroff, Steve; Jackson, Debra; Ramsey, Rosemary B.; Richmond, Jonathan Y. PHD  
Subject: RE: Shipping fetuses  
Importance: High

Susan,

Would you discuss Dr. Roffe's memo (attached below) with Dr. Kirshmack and then give me a call (via pager). As I mentioned during our telephone conversation, these animals were part of a planned research study. The protocol indicated that 50% of the infected animals were controls. Therefore, their aborted fetuses will be infected with Brucellosis. We/CDC just want to insure that appropriate shipping container are used when transporting infected animal carcasses. This was discussed in much detail (upfront) with both USDA and members of the research team (Dr's. Roffe, Drew, and Elzer) before CDC approved the project.

(P.S.) Please pass this e-mail on to Dr. Kirshmack. I'm not sure if I've spelled his name correctly.

Thanks,

Shanna Nesby-O'Dell DVM, MPH  
Chief, External Activities Program  
CDC-Office of Health and Safety  
Tele: (404) 639-4477 / Pager: (404) 280-7294  
E-mail: sln1@cdc.gov

-----Original Message-----

From: Roffe, Tom [mailto:troffe@montana.edu]  
Sent: Tuesday, March 26, 2002 6:13 PM  
To: 'Nesby, Shanna'; 'Foster, Joseph A.'; Hill, Robert H. Jr. (OD)  
Cc: 'Carter, Jon'; 'mark d'; 'bob h'; 'val r'; 'barb m'; 'phil e'; 'dick j'; 'larry l'; 'debra h'  
Subject: Shipping fetuses

Please see attached. Anyone wanting a hard copy let me know.

<<CDC shipping memo2.doc>>

tjr

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-----Original Message-----

From: Nesby, Shanna  
Sent: Monday, March 25, 2002 5:21 PM  
To: 'Roffe, Tom'; 'PElzer@agctr.lsu.edu'; mdrew@agri.state.id.us  
Cc: 'Valerie.E.Ragan@aphis.usda.gov'; Barbara.M.Martin@aphis.usda.gov  
Subject: RE: S19 vaccine efficacy in elk study  
Importance: High

Tom/Mark,

Today I spoke with Dr. Susan Gorsky at DoT Haz-Mat Division (202)366-9532. I explained the circumstances around the Elk Research Project and that we expect at least 50% of the aborted fetuses to be infected with Brucella (due to control animals). She agreed that this took your project out of the diagnostic category and into the 6.2 transport requirements for infectious substances. She indicated that for unique situations, DoT assesses the proposed packaging methods on a case-by-case bases to ensure regulatory compliance. She said you should contact Dr. Kirshmack (202-366-4493) in DoT's Exemption Branch to discuss your options.

I also have a suggestion on potential shipping containers. There's a company in Atlanta Georgia called: "Air-Sea"/ Tele: (404) 351-8600/ POC: Peter Roane. They sell a 12L pail/bucket with a resealable rubber gasket top. The kit is imported from England and it also include exterior boxes. We use the kit here at CDC to accommodate 6.2 shipping of odd shaped packages.

Please keep me in the loop on your resolve after speaking with DoT.  
Thanks, -Shanna-